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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,375	09/24/2001	Ikunoshin Kato	KATO18	8012

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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,375	KATO ET AL.	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26,40 and 42-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26 40 42-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Action is in response to the communication filed 11/10/03. Claims 1-26, 40 and 42-50 are pending in the application and are addressed herein.

2. It is noted that the response filed 11/10/03 was a reply to an Office Action that set forth an Election/Restriction requirement. Applicants' reply was not fully responsive because the Action set forth the requirement to elect a single species from each of six genus groups (e.g., a genus group comprising different species of functional substances with an affinity for the virus, etc.). In reply, Applicants elected a species from only one genus group (i.e., Applicants elected the species "cells" of the genus group comprising species of functional substances having an affinity for the target cell) and did not elect an appropriate species for the other genus groups set forth.

3. However, upon further consideration of the Election/Restriction set forth in the previous Office Action, it was determined that the Election/Restriction requirement may have been unclear and may not have clearly set forth the restriction groups. Furthermore, it was also determined that additional groups which require restriction are also present and further restriction therefore necessary. Therefore, for the reasons set forth herein, the previous restriction requirement is replaced with the restriction requirement set forth herein.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

It is noted that the claims encompass four (4) patentably distinct groups of Inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. These four groups, each of which further contain patently distinct groups of inventions that are not linked by unity of invention, are as follows:

Group I, claim(s) 1-7, 40 and 42-45, drawn to a composition that contains a functional substance that has affinity for a virus and also has an affinity specific for a target cell.

Group II, claim(s) 8-13, 40 and 42-45, drawn to drawn to a composition that contains two functional substances, one that has affinity for a virus and another that has an affinity specific for a target cell.

Group III, claim(s) 14-20 and 46-50, drawn to a method of using the composition of Group I.

Group IV, claim(s) 21-26 and 46-50, drawn to a method of using the composition of Group II.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the technical feature linking the Groups is a gene therapy composition generally described in claims 1 and 8. In order for a technical feature to be considered a special technical feature, it must be novel. In the instant case, the composition for gene therapy as described in claims 1 and 8 is not novel as evidence by US patent 5,830,880 (Hoechst Aktiengellschaft), as indicated in the international search report. Therefore, the technical feature linking the Groups is not novel and unity of invention does not exist.

However, as indicated above, each of the general groups I-IV must be further restricted because each general group comprises additional patently distinct groups (which are not linked by unity of invention). For instance, Group I is drawn to a composition that contains a functional substance that has affinity for a virus and also has an affinity specific for a target cell. These claims encompass 5 different groups of functional substances from which the affinity for the virus can be derived (see claim 3), 7 different functional substances from which the affinity for

the target cell can be derived (see claim 4), and 5 different groups of cell types from which the target cell can be derived (see claim 5).

Therefore, should Applicants wish to pursue the invention of Group I (indicated above), further group election of one (1) sub-group from ***each*** set of sub-groups below is required, ***as indicated***.

The subgroups of functional substances from which the affinity for the virus can be derived (see claim 3) are as follows: (Applicants must elect **one**)

Sub-group 1, claim(s) 3, drawn to a functional substance derived from anti-virus antibodies.

Sub-group 2, claim(s) 3, drawn to a functional substance derived from heparin-II-binding domain of fibronectin.

Sub-group 3, claim(s) 3, drawn to a functional substance derived from fibroblast growth factor.

Sub-group 4, claim(s) 3, drawn to a functional substance derived from collagen.

Sub-group 5, claim(s) 3, drawn to a functional substance derived from polylysine.

The subgroups of functional substances from which the affinity specific for the target cell can be derived (see claim 4) are as follows: (Applicants must elect **one**)

Sub-group A, claim(s) 4, drawn to a functional substance derived from proteins, each having an affinity for the target cell.

Sub-group B, claim(s) 4, drawn to a functional substance derived from hormones.

Sub-group C, claim(s) 4, drawn to a functional substance derived from cytokines.

Sub-group D, claim(s) 4, drawn to a functional substance derived from anti-target cell antibodies.

Sub-group E, claim(s) 4, drawn to a functional substance derived from sugar chains.

Sub-group F, claim(s) 4, drawn to a functional substance derived from carbohydrates.

Sub-group G, claim(s) 4, drawn to a functional substance derived from cells.

The subgroups of cell types from which the target cell can be derived (see claim 5) are as follows: (Applicants must elect **one**)

Sub-group i, claim(s) 5, drawn to a target cell derived from vascular endothelial cells.

Sub-group ii, claim(s) 5, drawn to a target cell derived from inflammatory cells.

Sub-group iii, claim(s) 5, drawn to a target cell derived from hematopoietic stem cells.

Sub-group iv, claim(s) 5, drawn to a target cell derived from brain endothelial cells.

Sub-group v, claim(s) 5, drawn to a target cell derived from bone marrow cells.

If the functional substance having an affinity specific for the target cell is a cell, then election of **one** (1) of the following sub-groups of cells is also required. The sub-groups of cells which the functional substance can be are as follows: (NOTE: Applicants must elect **one**, **ONLY if** the functional substance having an affinity for the target cell is a cell. If the functional substance having an affinity specific for the target cell is not a cell, then election is not required and claims 6 and 7 will be withdrawn from consideration)

Sub-group a, claim(s) 6 and 7, drawn to a vascular endothelial cell.

Sub-group b, claim(s) 6 and 7, drawn to an inflammatory cell.

Sub-group c, claim(s) 6 and 7, drawn to a hematopoietic stem cell.

Sub-group d, claim(s) 6 and 7, drawn to a brain endothelial cell.

Sub-group e, claim(s) 6 and 7, drawn to a bone marrow cell.

3. The inventions listed as sub-groups 1-5, A-G, i-v, and a-e, do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In order for a technical feature to be considered a special technical feature, it must be novel. In the instant case, the inventions listed are not novel as each of the sub-groups listed were known in the art, and were known in the art to be useful in gene therapy compositions. Additionally, in order for there to be unity of invention, the different elements of each subgroup encompassed by the

claims must share common structure and function. In the instant case, the elements of the different sub-groups do not share common structure and common function. Therefore, unity of invention does not exist, and restriction is proper.

It is noted that, with respect to Group I, claims 1, 2, 42 and 44 are linking claims that link the inventions of the different sub-groups.

Should Applicants wish to pursue the invention of Group II (indicated above), further group election of one (1) sub-group from ***each*** set of sub-groups below is required, ***as indicated***.

The subgroups of functional substances having an affinity for the virus (see claim 10) are as follows: (Applicants must elect **one**)

Sub-group 1, claim(s) 10, drawn to anti-virus antibodies.

Sub-group 2, claim(s) 10, drawn to heparin-II-binding domain of fibronectin.

Sub-group 3, claim(s) 10, drawn to fibroblast growth factor.

Sub-group 4, claim(s) 10, drawn to collagen.

Sub-group 5, claim(s) 10, drawn to polylysine.

The subgroups of functional substances having an affinity specific for the target cell (see claim 11) are as follows: (Applicants must elect **one**)

Sub-group A, claim(s) 11, drawn to proteins, each having an affinity for the target cell.

Sub-group B, claim(s) 11, drawn to hormones.

Sub-group C, claim(s) 11, drawn to cytokines.

Sub-group D, claim(s) 11, drawn to anti-target cell antibodies.

Sub-group E, claim(s) 11, drawn to sugar chains.

Sub-group F, claim(s) 11, drawn to carbohydrates.

Sub-group G, claim(s) 11, drawn to cells.

If the functional substance having an affinity specific for the target cell is a cell, then election of **one** (1) of the following sub-groups of cells is also required. The sub-groups of cells which the functional substance can be are as follows: (NOTE: Applicants must elect **one**, **ONLY if** the functional substance having an affinity for the target cell is a cell. If the functional substance having an affinity specific for the target cell is not a cell, then election is not required and claims 12 and 13 will be withdrawn from consideration)

Sub-group a, claim(s) 12 and 13, drawn to a vascular endothelial cell.

Sub-group b, claim(s) 12 and 13, drawn to an inflammatory cell.

Sub-group c, claim(s) 12 and 13, drawn to a hematopoietic stem cell.

Sub-group d, claim(s) 12 and 13, drawn to a brain endothelial cell.

Sub-group e, claim(s) 12 and 13, drawn to a bone marrow cell.

The inventions listed as sub-groups 1-5, A-G, and a-e, do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In order for a technical feature to be considered a special technical feature, it must be novel. In the instant case, the inventions listed are not novel as each of the sub-groups listed were known in the art, and were known in the art to be useful in gene therapy compositions. Additionally, in order for there to be unity of invention, the different elements of each subgroup encompassed by the claims must share common structure and function. In the instant case, the elements of the different sub-groups do not share common structure and common function. Therefore, unity of invention does not exist, and restriction is proper.

It is noted that, with respect to Group II, claims 8, 9, 42 and 44 are linking claims that link the inventions of the different sub-groups.

4. Additionally, Groups I and II contain claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If applicants wish to pursue the invention of either Group or Group II (indicated above), then Applicant is also required, in reply to this action, to elect **a single (1) species from each of the groups of species indicated below**, such that the elected species from each groups is the species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

5. The species of target cells are as follows (see claim 40):

i. hematopoietic stem cells
ii. blood cells
iii. leukocytes
iv. lymphocytes
v. T cells
vi. tumor-infiltrating lymphocytes
vii. B cells
viii. cancer cells

6. The species of therapeutic proteins are as follows (see claim 43):

i. an enzyme
ii. a cytokine

7. The species of virus (virus vectors) are as follows (see claim 45):

i. retrovirus vector
ii. adenovirus vector
iii. adeno-associated virus vector
iv. vaccinia virus vector

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-13, 40 and 42-45.

9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: In order for a technical feature to be considered a special technical feature, it must be novel. In the instant case, the species of target cells were known targets cells for gene therapy; the species of therapeutic proteins were known therapeutic proteins useful in gene therapy; and the species of viral vectors were all known viral vectors useful for gene therapy. Therefore, the technical feature linking the Groups is not novel and unity of invention does not exist.

Should Applicants wish to pursue the invention of Group III (indicated above), further group election of one (1) sub-group from ***each*** set of sub-groups below is required, ***as indicated***.

The subgroups of functional substances from which the affinity for the virus can be derived (see claim 16) are as follows: (Applicants must elect **one**)

Sub-group 1, claim(s) 16, drawn to a functional substance derived from anti-virus antibodies.

Sub-group 2, claim(s) 16, drawn to a functional substance derived from heparin-II-binding domain of fibronectin.

Sub-group 3, claim(s) 16, drawn to a functional substance derived from fibroblast growth factor.

Sub-group 4, claim(s) 16, drawn to a functional substance derived from collagen.

Sub-group 5, claim(s) 16, drawn to a functional substance derived from polylysine.

The subgroups of functional substances from which the affinity specific for the target cell can be derived (see claim 17) are as follows: (Applicants must elect **one**)

Sub-group A, claim(s) 17, drawn to a functional substance derived from proteins, each having an affinity for the target cell.

Sub-group B, claim(s) 17, drawn to a functional substance derived from hormones.

Sub-group C, claim(s) 17, drawn to a functional substance derived from cytokines.

Sub-group D, claim(s) 17, drawn to a functional substance derived from anti-target cell antibodies.

Sub-group E, claim(s) 17, drawn to a functional substance derived from sugar chains.

Sub-group F, claim(s) 17, drawn to a functional substance derived from carbohydrates.

Sub-group G, claim(s) 17, drawn to a functional substance derived from cells.

The subgroups of cell types from which the target cell can be derived (see claim 18) are as follows: (Applicants must elect **one**)

Sub-group i, claim(s) 18, drawn to a target cell derived from vascular endothelial cells.

Sub-group ii, claim(s) 18, drawn to a target cell derived from inflammatory cells.

Sub-group iii, claim(s) 18, drawn to a target cell derived from hematopoietic stem cells.

Sub-group iv, claim(s) 18, drawn to a target cell derived from brain endothelial cells.

Sub-group v, claim(s) 18, drawn to a target cell derived from bone marrow cells.

If the functional substance having an affinity specific for the target cell is a cell, then election of **one** (1) of the following sub-groups of cells is also required. The sub-groups of cells which the functional substance can be are as follows: (NOTE: Applicants must elect **one**, **ONLY if** the functional substance having an affinity for the target cell is a cell. If the functional substance having an affinity specific for the target cell is not a cell, then election is not required and claims 19 and 20 will be withdrawn from consideration)

Sub-group a, claim(s) 19 and 20, drawn to a vascular endothelial cell.

Sub-group b, claim(s) 19 and 20, drawn to an inflammatory cell.

Sub-group c, claim(s) 19 and 20, drawn to a hematopoietic stem cell.

Sub-group d, claim(s) 19 and 20, drawn to a brain endothelial cell.

Sub-group e, claim(s) 19 and 20, drawn to a bone marrow cell.

The inventions listed as sub-groups 1-5, A-G, i-iv and a-e, do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In order for a technical feature to be considered a special technical feature, it must be novel. In the instant case, the inventions listed are not novel as each of the sub-groups listed were known in the art, and were known in the art to be useful in methods gene therapy methods. Additionally, in order for there to be unity of invention, the different elements of each subgroup encompassed by the claims must share common structure and function. In the instant case, the elements of the different sub-groups do not share common structure and common function. Therefore, unity of invention does not exist, and restriction is proper.

It is noted that, with respect to Group III, claims 14 and 15 are linking claims that link the inventions of the different sub-groups.

Should Applicants wish to pursue the invention of Group IV (indicated above), further group election of one (1) sub-group from ***each*** set of sub-groups below is required, ***as indicated***.

The subgroups of functional substances having an affinity for the virus (see claim 23) are as follows: (Applicants must elect **one**)

Sub-group 1, claim(s) 23, drawn to anti-virus antibodies.

Sub-group 2, claim(s) 23, drawn to heparin-II-binding domain of fibronectin.

Sub-group 3, claim(s) 23, drawn to fibroblast growth factor.

Sub-group 4, claim(s) 23, drawn to collagen.

Sub-group 5, claim(s) 23, drawn to polylysine.

The subgroups of functional substances having an affinity specific for the target cell (see claim 24) are as follows: (Applicants must elect **one**)

Sub-group A, claim(s) 24, drawn to proteins, each having an affinity for the target cell.

Sub-group B, claim(s) 24, drawn to hormones.

Sub-group C, claim(s) 24, drawn to cytokines.

Sub-group D, claim(s) 24, drawn to anti-target cell antibodies.

Sub-group E, claim(s) 24, drawn sugar chains.

Sub-group F, claim(s) 24, drawn to carbohydrates.

Sub-group G, claim(s) 24, drawn to cells.

If the functional substance having an affinity specific for the target cell is a cell, then election of **one** (1) of the following sub-groups of cells is also required. The sub-groups of cells which the functional substance can be are as follows: (NOTE: Applicants must elect **one**, **ONLY if** the functional substance having an affinity for the target cell is a cell. If the functional substance having an affinity specific for the target cell is not a cell, then election is not required and claims 25 and 26 will be withdrawn from consideration)

Sub-group a, claim(s) 25 and 26, drawn to a vascular endothelial cell.

Sub-group b, claim(s) 25 and 26, drawn to an inflammatory cell.

Sub-group c, claim(s) 25 and 26, drawn to a hematopoietic stem cell.

Sub-group d, claim(s) 25 and 26, drawn to a brain endothelial cell.

Sub-group e, claim(s) 25 and 26, drawn to a bone marrow cell.

The inventions listed as sub-groups 1-5, A-G, and a-e, do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In order for a technical feature to be considered a special technical feature, it must be novel. In the instant case, the inventions listed are not novel as each of the sub-groups listed were known in the art, and were known in the art to be useful in methods gene therapy methods. Additionally, in order for there to be unity of invention, the different elements of each subgroup encompassed by the claims must share common structure and function. In the instant case, the elements of the different sub-

groups do not share common structure and common function. Therefore, unity of invention does not exist, and restriction is proper.

It is noted that, with respect to Group IV, claims 21 and 22 are linking claims that link the inventions of the different sub-groups.

10. Additionally, Groups III and IV contain claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If applicants wish to pursue the invention of either Group III or Group IV (indicated above), then Applicant is also required, in reply to this action, to elect **a single (1) species from each of the groups of species indicated below**, such that the elected species from each groups is the species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

11. The species of target cells are as follows (see claim 46):

i. hematopoietic stem cells
ii. blood cells
iii. leukocytes
iv. lymphocytes
v. T cells
vi. tumor-infiltrating lymphocytes
vii. B cells
viii. cancer cells

12. The species of therapeutic proteins are as follows (see claim 48):

i. an enzyme

ii. a cytokine

13. The species of virus (virus vectors) are as follows (see claim 50):

i. retrovirus vector
ii. adenovirus vector
iii. adeno-associated virus vector
iv. vaccinia virus vector

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 14-26, 46-50.

15. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: In order for a technical feature to be considered a special technical feature, it must be novel. In the instant case, the species of target cells were known targets cells for gene therapy; the species of therapeutic proteins were known therapeutic proteins useful in gene therapy; and the species of viral vectors were all known viral vectors useful for gene therapy. Therefore, the technical feature linking the Groups is not novel and unity of invention does not exist.

The restriction requirement between the linked inventions (i.e., the linked subgroups) is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such

claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

16. A telephone call was made to Sheridan Neimark on 2/6/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (571) 272-0756. The examiner can normally be reached on M-F (8:00-5:30) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J. Eric Angell, Ph.D.
Art Unit 1635

DAVE T. NGUYEN
PRIMARY EXAMINER